United States House of Representatives
Committee on Science

Hearing on:

"Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?"

Andrew D. Maynard, Ph.D.
Chief Science Advisor
Project on Emerging Nanotechnologies
Woodrow Wilson International Center for Scholars
Washington, DC

RESPONSE TO QUESTIONS FOR THE RECORD

September 21, 2006

10:00 a.m.

2318 Rayburn House Office Building

Questions for the Record Submitted by Chairman Sherwood Boehlert

QUESTION 1: In your testimony you indicated that the interagency working group is not able to carry out the important tasks identified in the Nanotechnology R&D Act, including assessing research gaps, setting priorities, and reviewing and directing agency budgets? How would you make NEHI more effective?

ANSWER: First, I would suggest that the NEHI working group's position under the National Science and Technology Council Committee on Technology places it at an immediate disadvantage in ensuring that targeted research informs regulation and other forms of oversight. I will expand on my reasoning behind this statement below. If NEHI does continue to be the interagency group primarily responsible for ensuring effective nanotechnology risk-research across the federal government, then I would propose that three changes are essential if the group is to be effective in implementing relevant parts of the 21st Century Nanotechnology Research and Development Act:

1. The charter of the NEHI working group must be modified to increase the group's charge and authority to establish and implement a strategic nano-risk research framework, which underpins nanotechnology oversight.
2. The NEHI working group must have the authority to ensure that appropriate agencies have the resources they need to conduct relevant, effective and coordinated risk research.
3. A full-time director, with appropriate staffing, must oversee the activities of the NEHI working group, with responsibility for developing and implementing a cross-agency strategic risk-research plan. The Director must be seen as an "honest broker" with no immediate ties to any government agency. The Director must also have direct access to key decision makers in both the White House and the Office of Management and Budget (OMB).

These changes will provide the tools NEHI needs to develop and implement an effective top-down strategic research framework across federal agencies, a framework that enables each agency to operate to maximum effect within its mission and competencies. However, by themselves, these changes will not guarantee success. Implementation of the recommended changes will require the support and commitment of all participating agencies, the Office of Science and Technology Policy (OSTP) and OMB. NEHI will also need new funding to cover critical research and support a full-time director. I have previously estimated that a minimum of $100 million over the next two years needs to be spent on targeted risk-related research, with additional funding for basic and applications-focused research with some relevance to understanding risk. I would suggest that mechanisms are needed whereby additional research funds can be allocated to agencies via the NEHI group to supplement current resource-starved programs—possibly through new funds being appropriated by a relatively neutral agency, and allocated out through interagency agreements. Effective resource allocation will depend on developing a strategic research agenda within NEHI, identifying the roles of research agencies within this agenda, and enabling cross-agency collaborations.

I also recommended in my testimony to the House Committee on Science that an external organization be used to allow public and private sector co-funding of strategic environmental, health and safety research. One model explored was the Health Effects Institute, which receives funding from the Environmental Protection Agency (EPA) (both the Office of Research and Development and the Air Office) along with industry to conduct targeted research on the health effects of air pollution.

Is NEHI the most appropriate cross-agency group to assess research gaps, set priorities, and review and direct agency budgets?

I would suggest that the NEHI working group's position under the National Science and Technology Council Committee on Technology places it at an immediate disadvantage in implementing risk-related aspects of the 21st Century Nanotechnology R&D Act, and in particular in ensuring that targeted research informs regulation and other forms of oversight. The paradigms and mechanisms that drive research for effective risk assessment and management differ significantly from those that drive basic science. There is a significant overlap between these two areas—applied risk-research will always build on basic science. But if applied research aimed at assessing and managing risk is approached in the same way as exploratory research, there is a danger that resulting research programs will not be responsive to the needs of regulators, industry and the public. The National Nanotechnology Initiative (NNI) has been extremely successful in stimulating exploratory research across many areas of science, which will underpin new applications and new ways of managing risk. Yet, there are indications that approaches to *applied* risk-research within the NNI are clouded by following an exploratory research-paradigm. I would highlight just three examples that support this observation:

- The current NEHI Terms of Reference focus on facilitating and supporting bottom-up research programs and strategies—an approach that is ideal for fostering collaborative investigator-driven exploratory research, but is not responsive to assessing research gaps, setting priorities, and reviewing and directing agency budgets.
- Current investment in risk-based research is purportedly dominated by the National Science Foundation (NSF)—despite a widely recognized need for targeted risk research beyond the directive of this agency. As nanotechnology moves off the lab bench and into the marketplace, one would expect to see a significant shift in risk-related research funding to mission-driven agencies such as the EPA, the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA), which have direct oversight responsibilities. This is not happening.
- The recent NSET research needs document[1] refers to current research, which, while conceivably enhancing our understanding of risk in the distant future, has little practical relevance at present. Take, for instance, the cited development of

[1] NSET. 2006. *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials.* Nanoscale Science, Engineering, and Technology Subcommittee, Committee on Technology, National Science and Technology Council. September.

Transmission Electron Aberration-corrected Microscope (TEAM) project within the Department of Energy (DOE).[2] From my own research, I can confidently state that, while this is a vital area of research for nano-applications, it is of only secondary importance to increasing our understanding of nano-implications.[3]

With the best will in the world, an effective strategic risk-research framework is unlikely to be developed and implemented if those responsible are working within the wrong paradigm, in an inappropriate framework. This is why, in my report on strategic risk research published earlier this year,[4] I recommend that a separate interagency group be established that can address these issues within an appropriate framework.

QUESTION 2: In your testimony you reported that the federal government is spending less on research on environmental and safety issues than the federal government claims it is spending. Why do your estimates differ so greatly with the figures reported by the Administration? What do you need to reconcile your figures with the government's accounting?

ANSWER: Based on the considerations outlined below, it is my opinion that the discrepancy between the NSET and the Project on Emerging Nanotechnologies (PEN) figures reflects a rather broad interpretation within NSET of research that is highly relevant to understanding the potential risks of engineered nanomaterials. Because federal agencies within the NNI remain unable to provide information on risk research at the project level, it is not possible to identify the sources of the discrepancy with any certainty.

Funding figures without access to the underlying data are largely meaningless. Understanding the potential risks of nanotechnology is complex, and identifying research that might provide insight is more than an accounting exercise. Because of this, the PEN inventory of health and environmental implications research[5] categorizes information in a way that captures the complexity of current research, and provides a resource for anyone interested in planning relevant, coordinated and strategic research. Open-access to the inventory also allows anyone to challenge or validate conclusions drawn from the information it contains. I would encourage the federal government to take a similar approach, and indeed would consider this essential for developing strategic research plans

[2] Ibid, p. 15.
[3] Maynard, A. D. 1995. "The application of electron energy-loss spectroscopy to the analysis of ultrafine aerosol particles." *J. Aerosol Sci.* 26(5): 757-777; Maynard, A. D. and L. M. Brown. 2000. "Overview of methods for analysing single ultrafine particles." 358(1775): *Philosophical Transactions of the Royal Society of London Series a-Mathematical Physical and Engineering Sciences*. 2593-2609; Maynard, A. D., Y. Ito, et al. 2004. "Examining elemental surface enrichment in ultrafine aerosol particles using analytical Scanning Transmission Electron Microscopy." *Aerosol Sci. Tech.* 38: 365-381.
[4] Maynard, A. D. 2006. *Nanotechnology: A Research Strategy for Addressing Risk.* Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, July. Available at: http://www.nanotechproject.org/reports.
[5] PEN. 2005. *Nanotechnology Health and Environmental Implications: An Inventory of Current Research.* Washington, DC: Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars. Available at: http://www.nanotechproject.org/18/esh-inventory.

that identify and address critical research needs. To achieve this, information must be collated, categorized and made available at the project level. An open accounting of the federal research portfolio would also make it easier for industry to determine where and how it could partner with government to fund risk research, as well as supporting effective international cooperation on strategic research.

Examining the differences between PEN and NSET risk research estimates

The NSET annual spending figure purportedly reflects research investment where the primary purpose is to understand and address potential risks to health and the environment. Research is either included in or excluded from the reported figures—there is no gray area of research that might have some relevance, but does not have a primary purpose of understanding risk. It must be assumed that interpretation of what constitutes relevant research is undertaken at the agency level and may be based on subjective judgments. Unfortunately, without information on which projects NSET does and does not account for, it is not possible to comment in depth on how this definition has been applied.

In contrast, the PEN inventory categorizes research according to its relevance to understanding risk (high, substantial, some or marginal), allowing an inherently more sophisticated assessment of current activity. In this scheme, *highly relevant research* is directly focused on addressing risk, while research having lesser relevance might be focused on applications of nanotechnology, general characterization methods or non-engineered nanomaterials. In addition, research into incidental nanomaterials (such as vehicle emissions and naturally occurring nanoparticles) is classified separately from research specifically focused on engineered nanomaterials. This distinction is important—research into the impact of incidental nanomaterials can help inform our understanding of nanotechnology risks, but it is misleading to account for it as being directly relevant to nanotechnology.

From the PEN inventory, it is estimated that the federal government invested $11 million on research, which is ***highly relevant to engineered nanomaterials*** in 2005 (Table 1). This added sophistication in accounting *might* explain some of the $28.7 million difference between PEN and NSET estimates. For instance, research on welding fume in the workplace—an incidental nanomaterial—has been included in the PEN inventory as it is useful for understanding purposely made nanomaterials. Yet this research has ***not*** been included in the estimated $11 million—precisely because it is ***not*** specifically focused on engineered nanomaterials. There is no way of telling at present whether the NSET has included this, and similar research projects, in spending estimates.

Table 1. Comparison of NNI-estimated annual nanotechnology risk-related research funding to estimates from the Project on Emerging Nanotechnologies. All figures are in $millions

Agency	NNI-estimated risk-related annual R&D	PEN-estimated risk-related annual R&D (highly relevant research)	Difference
NSF	24.0	2.5	21.5
DOD	1.0	1.1	- 0.1
DOE	0.5	0	0.5
HHS (NIH)	3.0	3.0	0
DOC (NIST)	0.9	0	0.9
USDA	0.5	0	0.5
EPA	4.0	2.3	1.7
HHS (NIOSH)	3.1	1.9	1.2
DOJ	1.5	0	1.5
Totals	38.5	10.8	28.7

The DOE, Department of Commerce (DOC), USDA and Department of Justice (DOJ) together account for a $3.4 million difference between the PEN and NSET figures. Information on what research DOJ is funding on nanotechnology risk research is not directly available, and is thus not included in the PEN inventory. For the other three agencies, it is likely that research accounted for by NSET as primarily addressing nano-risk was not considered *highly relevant* in the PEN inventory. For instance, a DOE project led by Dr. Kaufmann on controlling the shape, size and reactivity of metal oxide nanoparticles is categorized as having *substantial*, but not *high relevance* to risk in the PEN inventory. Likewise, a NIST project on developing microsphere-based spectroscopic instruments is categorized as having *marginal relevance* to risk in the PEN inventory. It is unclear whether NSET included these projects in its accounting.

The EPA and the National Institute for Occupational Safety and Health (NIOSH)—two federal agencies charged with supporting research to understand and reduce adverse health and environmental impacts—account for a $2.9 million difference between PEN and NSET figures. Discrepancies associated with EPA may well be due to differences in accounting—the NSET-reported figure for EPA includes a research investment in nanotoxicology grants for the period of fiscal year 2006 – fiscal year 2009, while the PEN figure reports mean annual EPA spending on risk-relevant research. Differences in the NIOSH estimates result from the lack of project-specific information being directly available from the agency. In the absence of further information, the reported $3 million per year investment was factored by the number of NIOSH projects in the PEN inventory that are *highly relevant* to understanding the potential risks of engineered nanomaterials.

By far the largest discrepancy is with estimated NSF funding—with a difference of $21.5 million per year between NSET and PEN. This is likely due to different interpretations of relevant research. Once again, I can only speculate on why the figures are so different, without NSET providing information at the project level. However, as an agency charged with funding basic research, it is surprising to see NSF purportedly accounting for over 60% of research where the primary purpose is to understand and address

potential risks to health and the environment—over three times the NSET-reported investment within NIOSH and EPA. This in itself is cause to question the figures.

The PEN inventory classifies many of the NSF projects as relevant to understanding risk, but not *highly relevant*. For instance, the NSF-funded Center for Biological and Environmental Nanotechnology (CBEN) at Rice University was considered *substantially relevant* to understanding risk, but the center's focus on applications as well as implications of nanotechnology precluded the research being categorized as *highly relevant*. Similarly, research into biologically compatible engineered nanoparticles to prevent UV-radiation induced damage was considered to have *some relevance* to risk, but not to be *highly relevant*.

Questions for the Record Submitted by Ranking Minority Member Bart Gordon

QUESTION 1: In responses to questions at the hearing, the agency witnesses seemed to be saying the current planning/coordinating mechanism for EHS research based on the NEHI working group will be able to produce an EHS research plan or roadmap, consisting of a cross-agency set of specific research priorities, timelines, and associated funding targets broken out by agency. Do you believe that there are adjustments that could be made to the way NEHI functions or to the way it is staffed that would allow it to achieve this goal in a timely way?

ANSWER: From my experience as co-chair of NEHI, my knowledge of the terms of reference of the working group and my observations of the group's activity over the past year, I can only conclude that NEHI will not be able to produce an EHS research plan consisting of a cross-agency set of specific research priorities, timelines, and associated funding targets broken out by agency, within an acceptable time frame. Let me qualify this by stating that the current members of NEHI are extremely well qualified to identify and assess what research needs to be done and by whom if the federal government's investment in nanotechnology research is to translate into responsible industries and products. The recent NSET report on research needs attests to this. Yet, NEHI lacks the terms of reference, authority and resources to achieve what is necessary, and members of the group are often juggling many other conflicting commitments to spend the necessary time on ensuring the group functions effectively. There is, as Chairman Boehlert observed during the hearing, a sense of *urgency* in this task as more nano-based products pour into the marketplace. It is not enough to ask the right questions, they must be asked early enough so that we have time to generate practical answers. Our ability to reap the long-term benefits of our investments in nanotechnology will depend heavily on how we address any emerging risks.

In my response to the first question from Chairman Boehlert (above), I consider three changes that I consider essential, if NEHI is to be effective in ensuring assessing research gaps are assessed, priorities are set, and agency budgets are reviewed and directed. Let me reiterate these changes here:

1. The charter of the NEHI working group must be modified to increase the group's charge and authority to establish and implement a strategic nano-risk research framework, which underpins nanotechnology oversight.
2. The NEHI working group must have the authority to ensure that appropriate agencies have the resources they need to conduct relevant, effective and coordinated risk research.
3. A full-time director, with appropriate staffing, must oversee the activities of the NEHI working group, with responsibility for developing and implementing a cross-agency strategic risk-research plan. The Director must be seen as an "honest broker" with no immediate ties to any government agency. The Director must also have direct access to key decision makers in both the White House and the Office of Management and Budget.

In my opinion, these changes will also enable NEHI to develop a strategic risk research framework, consisting of a cross-agency set of specific research priorities, timelines, and associated funding targets broken out by agency. Without significant changes to the way the group operates, I am extremely pessimistic that we will see an effective strategic research framework emerge that enables federal agencies to operate to the best of their ability when addressing the complex challenges that nanotechnology is raising.